

The Claims:

1. **(Original)** A cutting balloon for use on a medical catheter to incise tissue at a treatment site in a body vessel of a patient, said cutting balloon comprising:

an elongated balloon defining a longitudinal axis, said balloon being inflatable from a first deflated configuration to a second radially expanded configuration;

an elongated incising element mounted on said balloon and oriented longitudinally, said incising element having a length and extending radially from said balloon to an operative surface feature capable of incising tissue; and

a radially compressible sheath mounted on said balloon along the length of said incising element and extending radially from said balloon and beyond said surface feature when said balloon is in the first configuration to protect said surface feature during transit to the treatment site, said sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second configuration.

2. **(Previously Presented)** The cutting balloon as recited in claim 1 further comprising a mounting pad for attaching said incising element to said balloon.

3. **(Previously Presented)** The cutting balloon as recited in claim 2 wherein said incising element is partially encapsulated in said mounting pad and said mounting pad is bonded to said balloon.

4. **(Previously Presented)** The cutting balloon as recited in claim 2 wherein said sheath is attached to said mounting pad.

5. **(Previously Presented)** The cutting balloon as recited in claim 1 wherein said sheath comprises a pair of sheath members positioned on said balloon to interpose said incising element between said sheath members.

6. **(Previously Presented)** The cutting balloon as recited in claim 5 wherein each said sheath member is formed as a hollow tube.

7. **(Previously Presented)** The cutting balloon as recited in claim 5 wherein each said sheath member extends a radial distance, d , from said balloon when uncompressed and said incising element extends a distance, D , from said balloon, with $d > D$.

8. **(Previously Presented)** The cutting balloon as recited in claim 1 wherein said incising element is a blade and said surface feature is a cutting edge.

9. **(Previously Presented)** The cutting balloon as recited in claim 8 wherein said blade is partially encapsulated in a mounting pad, said mounting pad is bonded to said balloon, each said sheath member has an azimuthal width w , and wherein said blade has an azimuthal width, W , where said blade extends from said mounting pad, with $w > 2W$.

10. **(Previously Presented)** The cutting balloon as recited in claim 8 wherein said cutting edge of said blade is embedded in said sheath when said balloon is initially in said first configuration, said cutting edge oriented relative to said balloon to cut through said sheath for exposure of said cutting edge to incise tissue during radial compression of said sheath.

11. **(Previously Presented)** The cutting balloon as recited in claim 1 wherein said incising element is a round wire.

12. **(Previously Presented)** The cutting balloon as recited in claim 1 wherein said incising element is made of a hardened polymer.

13. **(Previously Presented)** The cutting balloon as recited in claim 1 wherein said sheath is made of a low durometer material.

14. **(Previously Presented)** The cutting balloon as recited in claim 1 wherein said sheath is made of a porous polyurethane material.

15. **(Original)** A cutting balloon for use on a medical catheter to incise tissue at a treatment site in a body vessel of a patient, said cutting balloon comprising:

an elongated balloon defining a longitudinal axis, said balloon being inflatable from a first deflated configuration to a second radially expanded configuration;

an elongated cutting blade mounted on said balloon and oriented longitudinally, said blade extending radially from said balloon to a cutting edge when said balloon is in said second configuration; and

a sheath for protecting said cutting edge during transit to the treatment site, said sheath having a pair of sheath members with each sheath member being shaped as a hollow, elongated tube and positioned longitudinally on said balloon to interpose said blade between said sheath members, each said sheath member made of a flexible material to radially compress between said tissue and said balloon to expose said cutting edge for tissue incision during an inflation of said balloon.

16. **(Previously Presented)** The cutting balloon as recited in claim 15 further comprising a mounting pad for attaching said blade to said balloon.

17. **(Previously Presented)** The cutting balloon as recited in claim 16 wherein said blade is partially encapsulated in said mounting pad, said sheath is attached to said mounting pad, and said mounting pad is bonded to said balloon.

18. **(Previously Presented)** The cutting balloon as recited in claim 15 wherein each said sheath member extends a radial distance, d , from said balloon when uncompressed and said blade extends a distance, D , from said balloon, with $d > D$.

19. **(Previously Presented)** The cutting balloon as recited in claim 15 wherein each said sheath

member is substantially rectangular shaped in a plane normal to said direction of tube elongation.

20. **(Original)** A cutting balloon for use on a medical catheter to incise tissue at a treatment site in a body vessel of a patient, said cutting balloon comprising:

an elongated balloon defining a longitudinal axis, said balloon being inflatable from a first deflated configuration to a second radially expanded configuration;

an elongated cutting blade mounted on said balloon and oriented longitudinally, said blade extending radially from said balloon to a cutting edge when said balloon is in said second configuration; and

a sheath for protecting said cutting edge during transit to the treatment site, said sheath having a pair of elongated sheath members with each sheath member being mounted longitudinally on said balloon and shaped to expose a preselected portion of said cutting blade for tissue incision when said sheath members are radially compressed between said tissue and said balloon during an inflation of said balloon.

21. **(Previously Presented)** The cutting balloon as recited in claim 20 wherein said blade has a first side and a second side and each said sheath member is in contact with a portion of a respective side to define said pre-selected exposed portion of said cutting blade.

22. **(Previously Presented)** The cutting balloon as recited in claim 20 further comprising a mounting pad for attaching said blade to said balloon.

23. **(Previously Presented)** The cutting balloon as recited in claim 21 wherein said blade is partially encapsulated in said mounting pad, said sheath is attached to said mounting pad, and said mounting pad is bonded to said balloon.

24. **(Previously Presented)** The cutting balloon as recited in claim 20 wherein each said sheath

member extends a radial distance, d , from said balloon when uncompressed and said blade extends a distance, D , from said balloon, with $d > D$.

Remarks

This Communication is in response to the Final Office Action dated **October 2, 2007**. In the Final Office Action, claims 1, 2, 8, and 10 were rejected under 35 USC 102(b) as being anticipated by Barath (5,616,149); claims 11-14 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149); claims 3-4 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Vigil (5,320,634); claim 5 was rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Shiber (6,730,105); claim 9 was rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Shiber (6,730,105) and Vigil (5,320,634); and claims 6, 7, and 15-24 were allowed.

The following comments are presented in the same order, with section headings, as the Office Action.

35 USC 102 - Barath

In the Final Office Action, claims 1, 2, 8, and 10 were rejected under 35 USC 102(b) as being anticipated by Barath (5,616,149).

Independent claim 1 recites in part “a radially compressible sheath ... being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second configuration.”

The Final Office Action stated

Applicant argues that the sheath in Barath does not radially compress to expose cutting edges. However, by nature of being between the tissue wall 7 and balloon 2, the sheath is radially compressed while exposing the incising element and therefore Barath reads on this claim limitation.

Applicants assert that Barath does not teach or suggest that the sheath is radially compressed to exposed the surface feature for tissue incision, as recited in instant independent claim 1. In reference to the fourth embodiment, Barath states:

“a protective sheath 17 covers the entire balloon” but that